on catecholamine receptor site, said method comprising the steps of:

administering at least one chemical compound, said chemical compound selected from among the group of catecholamine receptor site agonists, catecholamine site receptor antagonists, catecholamine analogs, catecholamine derivatives, and mixtures thereof; and

administering said chemical compound in an amount sufficient to effect a desired level of growth of said vectors and living organisms."

These claims were rejected in an Office Action mailed on September 25, 1992 for the following grounds and reasons:

I. Claims 1-23 were rejected under 35 U.S.C. 102/103 as unpatentable over Dyer et al. Or Moger et al. It was asserted that each of the references teaches the affecting of the growth of a vector or cell culture using a catecholamine. This was asserted to be what the Applicant was claiming, and therefore the claims were asserted to not be patentable.

II. Claims 1-23 were rejected under 35 U.S.C. 112, second paragraph as failing to particularly point out and distinctly claim the invention. Certain terms such as "vectors," "analogs" and "derivatives" were held to be indeterminate.

III. Claims 1-23 were rejected under 35 U.S.C. 102/103 as unpatentable over Kotimchenko et al. Or Sumanskii et al. Each of the references was asserted to show the use of a neurotransmitter chemical to affect the growth of "living organisms." No patentable distinction was seen between the process of the references and the process of the claims.

The response to this Office Action (filed on December 21, 1992) filed new claims 24-33. A restriction requirement, and an asserted constructive election was erroneously made, the restriction was made as between:

I. Claims 29-33 drawn to a method of diagnosis and glucose production, these claims being held to have been constructively non-elected since they were held to have been not previously examined and their subject matter is new. This assertion was clearly in error, as these claims are within the scope of original claim 1 filed in the Application and reproduced above.

II. Claims 24-25 drawn to methods of suppressing growth.

III. Claims 26-28 methods of suppressing growth with a catecholamine blocker.

The attorney of record canceled claims 29-33 and elected claims 24 and 25 for prosecution on the merits. These claims were rejected, an Amendment after Final Rejection was filed and refused admission by an Advisory Action. The Application was then refiled as a File Wrapper Continuation, with only claims 24-28 present in the Application.

It is to be noted that the "constructive election" (and hence a purported 'constructive restriction requirement') were not established under any legal standard, and that there is no regulatory or case law basis which attorney for applicant has found to allow such a practice. The MPEP, Chisum on Patents, and a Lexis-Nexis search on Federal case law after 1944 (searching for restriction and construct! W/3 elect!) found no citations on the topic. There apears to have been no basis for the "constructive election" and any attempt at a restriction requirement along the lines done would have been error and not a "proper restriction" requirement.

A true generic claim 1 as filed in the Application had been present, all of the claims subsequently submitted were subgeneric to that claim, and so the broad subject matter had been examined contrary to the position asserted in the Office Action to justify the "constructive election" which finds no basis in regulation, rule, statute or case law in the manner presented and with the facts presented. There was, therefore, no proper restriction requirement and no election of any sort against the subject matter presently encompassed by the claims for Reissue Patent filed with this application.

A potentially proper restriction requirement was then filed between claims 24-25 and 26-28 in an Office Action mailed January 31, 1995. These two groups of claims were directed at slightly different variants of suppression methods operating on Gram-positive bacteria, and neither of these methods are included within the scope of the new claims submitted for examination in this Reissue Application. Applicant, through his attorney of record, then elected claims 24-25 for prosecution on the merits. These claims were then rejected under 35 U.S.C.

112, first and second paragraphs. After another series of rejections, with only claims 24 and 34 in the Application, the two claims in the LYTE Patent were issued.

As is evident from the above comparison, original claim 1 of the LYTE Patent is limited to the method when employed to inhibit the growth of Gram-positive bacteria *in vitro* or in a cell culture. That is an extremely narrow process of little commercial utility. The original application as filed on March 6, 1992 clearly identified the scope of the invention as including enhancing the growth of bacteria and viruses *in vitro* and in cell cultures. Therefore, the LYTE patent is believed to be defective. New claim 3 recites no such limitations with respect to inhibiting growth in only Gram-positive bacteria. Accordingly, independent claim 3 is submitted to properly claim the broadest improvement over the methods of the prior art to which the patentee is entitled.

It is important to note that no restriction requirement in the Application filed on June 27, 1994 was ever asserted against the claims presented in the Reissue Application, so there is no applicability of issues found in *In re Orita, Yahagi, and Enomoti*, 193 USPQ 145, where it was held that "Although appellants undoubtedly erred by failing to file a timely divisional application in order to obtain a divisional patent, it does not follow that such error caused the original patent to be 'partially inoperative by reason of the patentee claiming less than he had a right to claim in the patent' as appellants aver in their reissue declaration under 37 CFR 1.175..." It was further stated in *In re Orita* that "...granting reissue claims substantially identical to those non-elected in application I would be ignoring the proper restriction requirement set forth in that application in which appellants acquiesced. Indeed, appellants' misapplication of section 251 would, if permitted, circumvent the copendency requirement of section 120 incorporated by reference in section."

The original restriction requirement was against

1) a method of diagnosing the presence of Gram-negative bacteria, including specific physical steps, none of which are recited in the claims of the Reissue Application;

2) a method of producing glucose from a lactose broth, the claim reciting specific physical steps which are not recited in the claims of the Reissue Application;

3) a method for suppressing the growth of Gram-positive bacteria; and

4) a specific method for suppressing the growth of Gram-negative bacteria comprising the introduction of an effective blocker of catecholamine receptor sites of the organisms. Methods 1), 2), 3) and 4) are clearly outside the scope of the claimed subject matter of the Reissue Application.

In comparing new claim 3 to original claim 1, claim 1 recites the step of "suppressing the growth of Gram-positive bacteria." Claim 3, however, does not include such a limitation, but instead recites "...enhancing the growth of bacteria or viruses.." This claim is not limited to suppression of growth, but only to enhancing of growth. The only actual restriction requirement which occurred in the prosecution of the U.S. Patent Application U.S. Serial No. 08/266,805 filed on June 27, 1994 was between:

I. Claims 24 and 25, drawn to a method of suppressing the growth of Gram-positive organisms with an amount of catecholamine, classified in Class 514, subclass 727.

II. Claims 26-28, drawn to a method of suppressing the growth of Gram-negative organisms by the introduction of an effective blocker of catecholamine receptor sites of the organisms, classified in Class 514, subclass 224.8.

The constructive election against claims 29-33 found in the parent application preceding U.S. Patent Application U.S. Serial No. 08/266,805 was not a proper restriction requirement, and was substantively incorrect even in its substance. In any event, the claims of the Reissue Application were not the subject of restriction requirements in U.S. Patent Application U.S. Serial No. 08/266,805. Therefore the claims submitted in this Reissue Application do not read on any species, elected invention or non-elected invention for which a proper restriction requirement was made.

In a similar comparison, independent method claim 12 was compared in the Reissue Declaration to original method claim 1 for purposes of discussion.

As is evident from that comparison, original claim 1 of U.S. Patent No. 5,629,349 is limited to the method when employed to inhibit the growth of Gram-positive bacteria. Accordingly, the claims exclude any useful method of increasing the supply of by-products from said bacteria or cell. The new claim 12 submitted in the Reissue Application encompasses this

useful method associated with the enhancement of bacteria or virus growth.

Each of reissue claims 4 through 11 and 13-20 depend from either reissue claim 3 or reissue claim 12, respectively. None of reissue claims 4-11 or 13-20 recite a limitation that reads on the subject matter which was restricted, non-elected, and effectively abandoned in the prosecution of U.S. Patent Application U.S. Serial No. 08/266,805 which ultimately issued as U.S. Patent No. 5,629,349 (hereinafter, the "Original Application"). Accordingly, reissue claims 4-11 and 13-20 differ from original claims 1 and 2 and are the proper subject matter for a Reissue Application.

The rejections in the Office Action in U.S. Patent Application U.S. Serial No. 08/266,805 mailed on September 25, 1992 included rejections of all claims (Claims 1-23) under 35 U.S.C. 102/103 as being unpatentable over Dyer et al., Moger et al., Kotimchenko, or Sukmanskii et al. These rejections were clearly explained to the attorney of record as being completely erroneous, at least for the following reasons:

A. The invention intended to be claimed was the enhanced growth of bacteria or viruses by the administration of catecholamines *in vitro* or in cell cultures. The enhanced growth was a result of the addition of the catecholamines.

B. Dyer et al. showed the stimulation of androgen production in ovarian cells when cultured in a serum-free medium. The mechanism proposed in the Chem Abstracts article was that the "catecholamine-augmented androgen prodn. Provides a direct link between the autonomic nervous system and regulation of ovarian steroid synthesis." That explanation has no logical bearing or relationship to the stimulation in the growth rate of bacteria or viruses, and none was implied by the article. The reference can neither anticipate the invention of Reissue Claims 3 and 12, nor provide a *prima facie* basis for a rejection under 35 U.S.C. 103.

C. Moger et al. teach that catecholamines stimulated androgen production by mouse interstitial cells in primary culture. The Chem Abstract text has no suggestion on the effect of catecholamine with respect to any cell growth, but only on the stimulation of androgen production. Again, that article has no logical bearing or relationship to the stimulation in the growth rate of bacteria or viruses, and none was implied by the article. The reference can neither anticipate the invention of Reissue Claims 3 and 12, nor provide a *prima facie* basis for a

rejection under 35 U.S.C. 103.

D. Khotimchenko describes the effect of adrenotropic substances (including ephedrine and noradrenaline) on the oocytes of sea urchins. This article has absolutely no logical relationship to the stimulation in the growth rate of bacteria or viruses, and none was implied by the article. The reference can neither anticipate the invention of Reissue Claims 3 and 12, nor provide a *prima facie* basis for a rejection under 35 U.S.C. 103.

E. Sukmanskii et al. teaches that certain hormones decreased the mitotic index of certain L-cells (reported in the NCBI PubMed QUERY printout as mice cells). The decrease of mitotic activity in mouse L-cells has absolutely no logical relationship to the stimulation in the growth rate of bacteria or viruses, and none was implied by the article. The reference can neither anticipate the invention of Reissue Claims 3 and 12, nor provide a *prima facie* basis for a rejection under 35 U.S.C. 103.

As can be seen from this analysis, the rejections of record were completely in error and should have been directly responded to on a substantive basis. In any event, the present claims of the Reissue Application contain narrowing limitations which effectively and clearly overcome those rejections.

The Examiner is invited to telephone the below-signed attorney at 612-373-6975 to discuss any questions which may remain with respect to the present application.

Respectfully submitted,

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Date 1 February 1999 By _____
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CERTIFICATE UNDER 37 CFR 1.10:
"Express Mail" mailing label number: EM287852441US Date of Deposit: February 1, 1999
I hereby certify that this paper or fee is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 on the date indicated above and is addressed to the Assistant Commissioner for Patents, Washington, D.C. 20231.

Chris Hammond _____
Name

Chris Hammond
Signature